Research Agreement and Research and Ethics Review Committee (RERC) Policy #AD 07-12-004

Purpose

The purpose of this policy is to outline the procedures for the review and approval of applications submitted to the Iowa Department of Public Health (IDPH) for access to IDPH data for use in a research project as allowed by statute or Administrative Code.

Definitions

Research: A systematic investigation designed primarily to develop or contribute to scientific, medical, public health or psychosocial disciplines and generalized knowledge and not for personal gain. Examples of "research" are included in **Appendix A**.

Data sharing agreement (DSA): A legal contract between IDPH and any external entity (including other departments within state government and Regent's institutions) in which parties agree to exchange specified variables within a dataset, or in some cases paper files, at identified intervals of time, and use of the data does not meet the conditions of initiating a research agreement.

Institutional Review Board (IRB): Also known as an independent ethics committee or ethical review board is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans. IDPH does not have an internal IRB; therefore, an external IRB approval may be sought by the researcher depending on the project partners.

Primary Investigator (PI): The individual conducting the research. The PI is responsible for the management of the research agreement. The PI is the point of contact for all communication with IDPH related to the review of the application and is also responsible for non-IDPH individuals who are authorized to access data received through the research agreement.

Research agreement: A contract between IDPH and any external entity (including other departments within state government and Regent's institutions) in which IDPH agrees to release specific variables within a dataset that includes parameters of time and geography as requested in a research application. A research agreement is required when the receiving entity intends to use the requested dataset for the purpose of research and is bound by the confidentiality requirements in the research agreement.

Research and Ethics Review Committee (RERC): The Research and Ethics Review Committee (RERC) is responsible for evaluating and approving or denying requests for IDPH-owned data. The committee composition, roles and responsibilities are outlined in this policy.

Policy

All applications for access to IDPH data requested for the purpose of research must be reviewed and approved by the Research and Ethics Review Committee (RERC). The RERC is also responsible for assuring documentation is sufficient to meet the requirements for committee review.

The duties of the RERC do not include review or approval of data sharing agreements where research is not the basis for the request.

The duties of the RERC do not include review or approval of Open Records requests. Open Records requests must be processed according to the procedures outlined in IDPH Policy# IM 11-04-015.

Procedures

Research and Ethics Review Committee (RERC)

Duties of the RERC

The RERC is responsible for receiving and processing all applications for research agreements and research-related requests for IDPH data. This includes applications from IDPH staff and non-IDPH staff. The following sections detail the procedure for processing research agreement applications and research-related requests.

All applications will be placed in queue for RERC review upon receipt of necessary documentation from the PI. After receipt of the complete application, the documents will be reviewed and a response provided to the PI typically within one month, but no more than three. The timing of reviews and final decisions is dependent on completeness of the application, PI responsiveness to comments or questions from the RERC, and the number of applications under review at that time.

Composition of the RERC

The committee will have three permanent members designated by Executive Team:

A. Bureau Chief for the Bureau of Health Statistics (Vital Statistics)
B. IDPH Medical Director/State Epidemiologist (Deputy State Epidemiologist may serve in the absence of the Medical Director)
C. Data Management Program Manager or other comparable individual in a position with duties that include IDPH data management.

The committee may have additional members meeting the following criteria:

- Must have work experience and/or academic training in health statistics, research methodology or epidemiology of acute or chronic disease.
- A temporary subject matter expert (e.g., data owner, steward, custodian, or in some cases a bureau chief or other administrator).

Quorum criteria

- Decisions are made by consensus, when at least two permanent members must agree.

Application Requirements for IDPH Research Agreements- *New and Continuing*

All <u>NEW</u> applications submitted to the RERC for consideration must include the following documents:

- Application for research agreement
- List of requested variables or files
- Copy of IRB application (all documentation required) and approval or exemption*
- Resume or biosketch

*Conditional project approval may be granted when IRB approval is pending; however, no data will be released until IRB approval is obtained and submitted to IDPH.

After approval of the **<u>NEW</u>** application, the PI will be asked to complete the following:

- Research agreement between IDPH and PI, including additional signature page for other persons involved in the project

- Confirmation of Destruction form

All applications submitted to the RERC for consideration for <u>CONTINUATION</u> must include the following documents:

- Current Research Agreement #, date current Agreement was effective, and a description of any changes in the research project
- Updated application for research agreement
- List of requested variables or files
- Copy of updated IRB application (all documentation required) and approval or exemption*

*Conditional project approval may be granted when IRB approval is pending; however, no data will be released until IRB approval is obtained and submitted to IDPH.

After approval of the **<u>CONTINUATION</u>** application, the PI will be asked to complete the following:

- Research agreement between IDPH and PI, including additional signature page for other persons involved in the project
- Confirmation of Destruction form

In addition to providing the necessary documentation, the RERC will assess whether proposals meet the following requirements:

- IDPH possesses the legal authority to release or withhold the data requested.
- Knowledge gained from this research agreement must contribute to the understanding of health conditions or to an issue related to public health and be of intrinsic value to the people of Iowa. Must be bona fide research and not conducted for personal gain[1].
- Data requested must be used **for research purposes only**. The data may not be transferred or reused by the Primary Investigator (PI) without seeking explicit and additional approval of the RERC. IDPH data may never be given or sold by a PI or other person(s) or entities, unless authorized by the original agreement.
- Research must include ethical and legal considerations within the study design.
- Research must include realistic outcomes or goals.
- PI must verify the means to compensate IPDH for any charges resulting from the fulfillment of the research agreement (e.g., data retrieval fees).
- PI must submit all required documentation for review by the RERC (see application checklist for list of documents).
- PI must provide documentation of their application to Institutional Review Board (IRB) and the decision of the IRB, if applicable.
- PI must adhere to contract data security standards outlined in the research agreement.
- PI must provide drafts of any public presentation (e.g., manuscripts, presentation) containing IDPH data for pre-approval by the Data Management Program Manager. PI is responsible for oversight of any public presentation of IDPH data. IDPH data may be presented without RERC authorization within the data release guidelines outlined in the research agreement. Questions surrounding pre-approval of data presentation may be submitted to the RERC at any time.
- PI must agree to submit a continuation request, if needed.
- PI must confirm destruction of data, which may include confirming data destruction by an uninvolved or impartial third party.

The RERC reserves the right to request documentation outside of the parameters listed in the policy.

Consultation with the RERC prior to submission of application may be appropriate under certain circumstances. The RERC is available for consultation on release concerns and guidance when an application is needed or not necessary.

[1] 641.175.10(2)(b)

Any data release to an external entity that has not been approved via this process must follow the policy for *Disclosure of Confidential Public Health Records*.

Expiration of Research Agreement

The term of the Research Agreement is two years from the starting effective date, unless terminated early in accordance with section VI of the Research Agreement. If the PI anticipates their project continuing past the expiration date, they must resubmit an application for continuation of the agreement at least 60 days prior to the expiration date of the agreement so that there is no lapse.

If the PI does not submit an application for continuation of the Research Agreement they must destroy the data in compliance with the *Security Rules for IDPH Data.* In addition, the *Confirmation of Destruction* form must be completed and returned to the RERC upon completion of the project. This must be done within 60 days of the expiration date of the agreement or completion of the project, whichever occurs soonest, unless an application for continuation has been submitted.

Policy/Procedure Violations

For all persons and entities participating in a research agreement with IDPH - IPDH has the authority to employ penalties for misuse of data. Penalties for violations of the research agreement may include, but are not limited to:

- Revocation of the research agreement and notice to the immediate supervisor of the violating PI.
- Notice of revocation of the research agreement to the entity's director.
- Immediate destruction of data confirmed by independent third party, and may need to be verified by IDPH.
- Future requests by the violating PI and other implicated investigators may be denied.
- Other sanctions as authorized by federal or state law.

The PI is responsible for all violations of the research agreement for all co-signatories of the agreement.

Appendix A- Policy #AD 07-12-004

Examples of Research and Non-Research Requests

The following are examples of situations when requests for access to data, either from outside IDPH or from IDPH staff, MUST be reviewed by the RERC.

Example A

A researcher is requesting access to five years' worth of birth certificate data. The data requested does not contain patient-identifying information, but will be used as part of a research project.

Explanation A

Data are being used for a research project. It does not matter whether the data will contain identifying information. All requests for data used in a research project must be routed through the process for approval through the RERC.

Example B

A University of Iowa graduate student is working on a project in which they need access to data from the Iowa Registry of Congenital and Inherited Disorders.

Explanation B

Although the registry is maintained at the University of Iowa, it is still owned by IDPH. The student would need to submit an application to the RERC as well as receive a letter of agreement from the director of the registry.

Example C

The Iowa Department of Human Services (DHS) is conducting a study to determine the percentage of low-income Iowa residents who are eligible for Medicaid that enroll in Medicaid either through IDPH or DHS. DHS is requesting the list of Iowa residents enrolled in Medicaid-sponsored maternal and child health programs, including patient names. DHS plans to publish the results of this study in a professional health journal with the intent to increase physician awareness of Medicaid enrollment statistics.

Explanation C

Even though the requestor of data in this example is another state agency, the agency is using the data for a research project. Anytime IDPH data might be used for research or publication, the request for data must go through the RERC.

The following are examples of situations when requests for access to data, either from outside IDPH or from IDPH staff, Do NOT need to be reviewed by the RERC.

Example E

The National Marrow Donor Registry has requested that IDPH match the list of eligible Iowa donors to Iowa residents who have died in the past year. The Donor Registry is making this request so that the Registry has a current list of donors.

Explanation E

This request does not involve use of the data for research; however, a data sharing agreement must be in place before data may be shared.

Example F

The Iowa Department of Human Services (DHS) is evaluating the percentage of low-income Iowa residents who are eligible for Medicaid that enroll in Medicaid either through IDPH or DHS. DHS is requesting the list of Iowa residents enrolled in Medicaid-sponsored maternal and child health programs, including patient names. The results of the evaluation are being used to assess DHS programs and will not be released outside of their department.

Explanation F

Other state agencies may request data from IDPH for use internally. A data sharing agreement is sufficient as long as the data is not released outside of the agency and is not used as part of a research project.